

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

TAMMY ALLEN, PERSONAL REPRESENTATIVE
OF THE ESTATE OF NORMAN ALLEN

Plaintiff,

v.

UNITED STATES OF AMERICA

Defendant.

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) Case No. 05-11463-DPW
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AFFIDAVIT OF JAMES A. TALCOTT, M.D.

I do hereby state the following under the pains and penalties of perjury:

1. I submit the following Affidavit regarding the facts of this case and the claim that the failure of Norman Allen to undergo a screening procedure for colorectal cancer contributed to his death.
2. I am a physician licensed to practice medicine in Massachusetts. I am Board Certified in Internal Medicine and Medical Oncology. I am an Associate Professor of Medicine at Harvard Medical School and an Associate Physician at Massachusetts General Hospital in Boston, Massachusetts.
3. I am not an expert in the standard of care for a primary care provider. However, I am familiar with the issues regarding cancer screening and the principles of cancer growth and metastasis.
4. Mr. Allen was under the care of Dr. Michael Kelly for several years. Between February 1998, when he had turned 50, and September 1999, when he changed his primary care physician, Mr. Allen had numerous medical problems. While the medical record does not document that Mr. Allen did not receive colorectal screening, Dr. Kelly testified that giving guaiac cards to patients for screening was a regular is a regular, but undocumented, part of his practice.
5. On 7/13/99, Mr. Allen reported intermittent bloody stools to Dr. Robert Simms, a consultant for his fibromyalgia. The patient underwent colonoscopy on 10/20/99, 23 days after his new primary care provider, Dr. David Farzan noted his history of rectal bleeding and referred him to Dr. Thomas Fazio, a gastroenterologist, to evaluate him. The colonoscopy found a 3 cm moderately differentiated tumor located 6 cm from the rectum. At surgery on 12/1/99, he was found to have cancer in 1 of 6 sampled lymph nodes, resulting in the diagnosis of Stage III colon cancer.

6. He subsequently underwent chemotherapy and radiation therapy, which was complete in the fall of 2000. Nevertheless, he had extensive metastatic cancer diagnosed in his liver in April 2002, leading to his death the following month.

7. I have been asked comment on whether the patient's failure to undergo screening for colorectal cancer contributed to his death. His cancer was diagnosed a little over 8 cm from the anal verge, so the cancer would not have been diagnosed by a rectal exam, and in fact it was not identified in rectal examinations performed in his GI workup. Therefore, my comments focus on invasive or radiographic screening tests.

8. My opinion on this case requires reference to broader principles of cancer screening, prognosis and tumor kinetics. One result of successful cancer screening is diagnosis of cancers at an earlier stage. However, the goal of early diagnosis is to identify disease at a stage at which treatment is more successful. Earlier stage cancers are not necessarily more curable, although medical trials indicate that fewer patients die of colorectal cancer after one of the screening methods than when they do not undergo screening, although the strength of the available supporting data varies by screening method. Virtually all solid tumors, such as rectal cancer, are curable only when the cancer has not spread to other parts of the body, or metastasized, so that surgery, or in some cases radiation therapy, results in the removal or destruction of all cancer cells in the body. The cause of death from cancer, other than the unusual case of tumors located near critical organs, such as brain tumors, is metastatic cancer, not the primary tumor, such as the one that was found in Mr. Allen's rectum. Therefore, not all cancers diagnosed by screening are curable. If Mr. Allen's cancer had already metastasized, or spread through the bloodstream to other parts of the body, surgery would have not been curative.

9. Further, the most aggressive and dangerous cancers grow so fast that screening does not detect them. Rather, they progress to the point where they cause symptoms that prompt diagnostic procedures between scheduled screens. Such cancers are called "interval cancers" because they become apparent in the interval between regular screens.

10. While cancer prognosis is statistically correlated with clinical stage at diagnosis, that association does not hold for every patient, and it cannot be stated that diagnosis at an earlier stage indicates a curable cancer that is subsequently cured. Clinical staging is a rough process that uses important clinical factors to stratify patients by average prognosis, but the prognosis of patients within a single clinical stage may vary widely. In part, this is due to medicine's imprecision in determining the extent of cancer, the primary basis for most cancer staging systems, particularly the limited ability to detect more advanced cancer, especially in small amounts. Large numbers of cancer cells are required for medical detection. A cc of cancer cells, which is comprised of 10 to 100 billion cells, is generally regarded as the minimum size for detection. For a single malignant cell to progress by cell divisions or "doubling" to achieve that mass require approximately 25 to 34 cell divisions. It is firmly understood in oncology that patients in a lower stage may differ little from patients in a higher stage, since they may be distinguished only by a small difference in the amount of tumor on which the stage difference is based. If the more extensive cancer is detectable, the patient is assigned to the higher stage, if not, to the lower stage. Such a tumor mass may undetectable by one test but found by a more sensitive test. In fact, improving technology over time that results in better detection of advanced

cancers, producing higher average stages as a result was described in a landmark scientific paper as stage migration, or the Will Rogers phenomenon.

11. Clinical stage alone, even if determined accurately, does not determine prognosis. Other factors may have important prognostic implications. It is well established that the rate of growth of a cancer is a very important indicator of prognosis. This information is not readily incorporated into clinical staging systems because it can only be determined over time, so it is not available in the short interval when initial treatment decisions are being made.

12. We can make some assumptions about the behavior of Mr. Allen's cancer. We do know that metastatic cancer was found in one of Mr. Allen's lymph nodes in October 1999, the result that determined that he had a Stage III cancer. It is clear that the metastasis must have established itself earlier. A cancer which doubles within a month, a rapid rate for a colon cancer, would have first invaded the lymph node 25 to 34 months before it was detected in late 1999 to achieve a 1 cc size, which would establish its origin in 1996 or 1997. Screening in 1998 or 1999, even if it diagnosed the cancer, would not have preceded the establishment of a lymph node metastasis.

13. The subsequent behavior of the tumor provides important information additional to the stage at diagnosis, indicating that Mr. Allen's cancer was an aggressive, rapidly-growing tumor. Metastatic cancer had virtually replaced Mr. Allen's liver by April 2002, less than 2-1/2 years after his cancer was diagnosed, despite the fact that he had completed a full course of adjuvant chemotherapy and radiation, and the cancer resulted in his death within another month. This rapid metastatic progression indicates the very biologically aggressive nature of his cancer, which is also consistent with the nerve and vascular invasion seen in his biopsy specimen. Such aggressive cancers are less likely to be diagnosed by screening tests when curable.

14. I agree with the other consultants that the period between when Dr. Kelly was notified of the history of rectal bleeding given to Dr. Farzan and his referral to Dr. Fazio in late September 1999 did not materially affect the patient's outcome. Further, it is my judgment to a medical degree of certainty that failing to obtain colorectal cancer screening some time after February 1998 did not contribute to his death from colon cancer, since it is likely he had microscopic metastatic colon cancer prior to that time. Further, judging from the behavior of his cancer after diagnosis, he had an aggressive, rapidly-growing cancer that was unlikely to be detected at a curable stage by screening.

Sincerely,

James A. Talcott, MD SM

On this ____ day of _____, 2007, before me, the undersigned notary public, personally appeared _____ (name of document signer), proved to me through satisfactory evidence of identification, which were _____, to be the person whose name is signed on the preceding or attached document in my presence.

(official signature and seal of notary)

My commission expires _____